Complete Summary

GUIDELINE TITLE

Stereotactic radiosurgery for patients with metastatic brain tumors.

BIBLIOGRAPHIC SOURCE(S)

International RadioSurgery Association (IRSA). Stereotactic radiosurgery for patients with metastatic brain tumors. Harrisburg (PA): International RadioSurgery Association (IRSA); 2008 May. 24 p. (Radiosurgery practice guideline report; no. 5-08). [135 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Brain metastases (metastatic brain tumors)

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Neurological Surgery
Neurology
Oncology
Radiation Oncology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Hospitals
Managed Care Organizations
Nurses
Patients
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

- To develop an evidence and consensus-based radiosurgery practice guideline for brain metastases treatment recommendations to be used by medical and public health professionals who diagnose and manage patients with brain metastatic disease
- To improve outcomes for brain metastases radiosurgery by assisting physicians and clinicians in applying research evidence to clinical decisions while promoting the responsible use of health care resources

TARGET POPULATION

Patients diagnosed with metastatic brain disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Pre-radiosurgery evaluation including high resolution double dose contrast-enhanced magnetic resonance imaging (MRI) (or computed tomography [CT])
2. Stereotactic radiosurgery (SRS) (alone or as a boost after whole-brain radiation therapy [WBRT]) using Gamma Knife, proton beam, or dedicated linear accelerators
3. Corticosteroids (a single stress dose) at the conclusion of radiosurgery procedure
4. Chemotherapy
5. Other medications (e.g., anticonvulsants, antiedema drugs)
6. Follow up including MRI scans at specific intervals
7. Surgical decompression for patients with large tumors causing symptomatic mass effect

MAJOR OUTCOMES CONSIDERED

- Tumor growth control
- Overall survival
- Recurrence rate

- Functional improvement
- Adverse events
- Quality of life
- Overall patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

MEDLINE and PUBMED searches were completed for the years 1966 to May 2008. Search terms included: brain metastases, metastatic brain tumor, stereotactic radiosurgery, Gamma Knife®, linear accelerator, irradiation, clinical trials, research design, practice guidelines and meta-analysis. Bibliographies from recent published reviews were reviewed and relevant articles were retrieved.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

This classification is based on the Bandolier system (http://www.medicine.ox.ac.uk/bandolier/band6/b6-5.html) adapted for a systematic review.

Type & Strength of Evidence in Medical Literature

Type I: Evidence from a systematic review (which includes at least one randomized controlled trial and a summary of all included studies).

Type II: Evidence from a well designed randomized controlled trial of appropriate size.

Type III: Evidence from a well designed intervention study without randomization. A common research design is the before-and-after study.

Type IV: Evidence from a well designed non-experimental study, e.g., cohort, case-control or cross-sectional studies. (Also includes studies using purely

qualitative methods. Economic analyses [cost-effectiveness studies] are also classified as Type IV evidence.)

Type V: Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert consensus committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The literature identified was reviewed and opinions were sought from experts in the diagnosis and management of brain metastases including members of the working group.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The working group included physicians and physicists from the staff of major medical centers that provide radiosurgery. The initial draft of the consensus statement was a synthesis of research information obtained in the evidence gathering process.

Members of the working group provided formal written comments that were incorporated into the preliminary draft of the statement. No significant disagreements existed.

The final statement incorporates all relevant evidence obtained by the literature search in conjunction with the final consensus recommendations supported by all working group members listed in the original guideline document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were e-mailed to all committee members. Feedback was obtained through this e-mail survey consisting of proposed guidelines asking for comments on the guidelines and whether the recommendation should serve as a practice guideline. No significant disagreements existed.

This practice guideline, together with a report on "Metastatic Brain Tumor Management" is an original guideline approved by the International RadioSurgery Association and issued in May 2008.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

- Patients with brain metastases, defined by modern neurodiagnostic imaging (computed tomography [CT], magnetic resonance imaging [MRI] scan) constitute the study group. Such patients typically present with seizures or symptoms of mass effects such as headache, nausea, vomiting, weakness, numbness of limbs or speech problems. Many patients' tumors are detected due to MRI surveillance before they develop any symptoms.
- Stereotactic radiosurgery is a minimally invasive, single session, high-dose, closed skull strategy that may be especially suitable for patients who have limited metastatic brain disease and have controlled systemic disease with good functional status.
- Stereotactic radiosurgery is typically employed alone or as a boost after whole-brain radiation therapy (WBRT) for patients with metastatic brain tumors.
- A high resolution double dose contrast-enhanced MRI is usually necessary to determine the number of metastatic tumors. For radiosurgery dose planning, double dose contrast-enhanced volumetric gradient recalled MR stereotactic images are ideal.
- Current radiation delivery technologies for volumetric stereotactic conformal single session radiosurgery include Gamma Knife®, proton beam using Bragg peak effect, and specially modified or dedicated linear accelerators like Novalis Tx™ and Axesse™.
- The optimal dose range for volumetric conformal stereotactic brain metastases radiosurgery has been largely established based on tumor anatomy (proximity to eloquent brain regions), tumor volume, prior radiation therapy and estimated adverse radiation risks. Minimum doses to the margin typically range from 14 to 24 Gy in a single session.
- Patients may receive a single stress dose of corticosteroids at the conclusion of the radiosurgery procedure. Patients can continue to take other medications (antiseizure or antiedema drugs) as recommended by their physicians.
- Post-radiosurgical clinical examinations and MRI studies are requested by referring physicians at 2 to 3 month intervals or earlier if the patient develops a new symptom suggestive of a new tumor, brain edema or hemorrhage.
- Patients with large tumors causing symptomatic mass effect may need surgical decompression of the tumor. Residual tumor or tumor bed can be treated by radiosurgery or radiation therapy.

- Causes for local failure of stereotactic radiosurgery include inadequate visualization of the tumor, lack of intraoperative stereotactic three-dimensional (3-D) (volumetric) imaging, new metastatic deposits and insufficient dose (due to large tumor volume and proximity to eloquent brain locations) to achieve the growth control response.

CLINICAL ALGORITHM(S)

Algorithms are provided in the original guideline document for:

- Brain Lesion Suggestive of Metastasis on Magnetic Resonance Imaging (MRI)
- Single Brain Metastasis on MRI
- Limited (2–4) Brain Metastases on MRI
- Multiple (>4) Brain Metastases on MRI

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Type I, II, and III evidence exists in support of stereotactic radiosurgery for brain metastases. Refer to the "Rating Scheme for the Strength of the Evidence" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Improved management of patients with brain metastases

Specific Benefits

Benefits of *radiosurgery* include minimally invasive approach and high rates of tumor growth control (80 to 90%).

Subgroup(S) Most Likely to Benefit

- Patients diagnosed with small to medium size brain metastases without symptomatic brain compression.
- Patients with residual or recurrent brain metastases after resection.
- Patients with residual or recurrent brain metastases after whole-brain radiotherapy (WBRT).

POTENTIAL HARMS

- Major adverse effects of radiosurgery are based on location, volume, and dose, and these risks can be estimated based on published data and experience. Individual risks are related to the anatomic location of tumors.
- The overall side effects of stereotactic radiosurgery (SRS) are limited but can occasionally be serious. There are very few acute side effects of SRS related

to the radiation. Stereotactic radiosurgery may cause mild fatigue and sometimes a temporary patch of hair loss if the tumor is close to the skull and scalp. There is a risk of late side effects that can develop, the most common and serious of which is tumor radionecrosis. Radiation necrosis is damage to the tumor and/or adjacent brain in the high-dose area. This can result in edema and additional side effects produced by the mass including seizures and neurological deficits. Radionecrosis can often be managed with corticosteroids. Occasionally surgical intervention is required to reduce the mass effect. The risk of symptomatic radionecrosis is usually less than 5%.

Subgroup(s) Likely to Be Harmed

Patients with large volume tumors causing symptomatic mass effect on the brain.

CONTRAINDICATIONS

CONTRAINDICATIONS

Brain metastasis diameter greater than 4 cm is a relative contraindication dependent upon individual circumstance.

QUALIFYING STATEMENTS

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- This guideline is intended to provide the scientific foundation and initial framework for the person who has been diagnosed with a vestibular schwannoma. The assessment and recommendations provided in this guideline represent the best professional judgment of the working group at this time, based on research data and expertise currently available. The conclusions and recommendations will be regularly reassessed as new information becomes available.
- This guideline is not intended as a substitute for professional medical advice and does not address specific procedures or conditions for any patient. Those consulting this guideline are to seek qualified consultation utilizing information specific to their medical situation. Further, International RadioSurgery Association (IRSA) does not warrant any instrument or equipment nor make any representations concerning its fitness for use in any particular instance nor any other warranties whatsoever.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 May

GUIDELINE DEVELOPER(S)

IRSA - Professional Association

SOURCE(S) OF FUNDING

IRSA (International RadioSurgery Association)

GUIDELINE COMMITTEE

The IRSA Medical Advisory Board Guidelines Committee and representatives in the industry.

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The radiosurgery guidelines group is comprised of neurosurgeons, neuro-oncologists, radiation and medical oncologists and physicists. Community representatives did not participate in the development of this guideline.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

IRSA makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of a personal, professional, or business interest of a member of the radiosurgery guidelines group.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available Portable Document Format (PDF) from the IRSA Web site.

Print copies: Available from the IRSA (International RadioSurgery Association), 3002 N. 2nd Street, Harrisburg, PA 17110

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

The following is available:

- Metastatic brain tumors –the real crisis. Another perspective. 2000;5(2)1-12. Electronic copies: Available in Portable Document Format (PDF) from the IRSA Web site.

Print copies: Available from the IRSA, 3002 2nd Street, Harrisburg, PA 17110.

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NGC STATUS

This NGC summary was completed by ECRI Institute on August 22, 2008. The information was verified by the guideline developer on September 23, 2008.

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Date Modified: 11/3/2008


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